



January 26, 2015

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Alcon Laboratories, Inc.
Ms. Alicia M. Plesnarski, RAC
Director, Regulatory Affairs, Alcon Vision Care
6201 South Freeway
Fort Worth, TX 76134

Re: K142284
Trade/Device Name: CLEAR CARE[®] PLUS Cleaning & Disinfecting Solution
Regulation Number: 21 CFR 886.5928
Regulation Name: Soft (hydrophilic) contact lens care products
Regulatory Class: Class II
Product Code: LPN, MRC
Dated: December 15, 2014
Received: December 17, 2014

Dear Ms. Plesnarski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).

You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Kesia Y. Alexander -S

for Malvina B. Eydelman, M.D.

Director

Division of Ophthalmic and Ear, Nose,
and Throat Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K142284

Device Name

CLEAR CARE PLUS Cleaning & Disinfection Solution

Indications for Use (Describe)

CLEAR CARE PLUS Cleaning & Disinfecting Solution is indicated for use in simultaneous cleaning, daily protein removal, disinfection, and storing of soft (hydrophilic) contact lenses (including silicone hydrogel lenses) and rigid gas permeable (fluoro silicone acrylate and silicone acrylate) contact lenses, as recommended by your eye care professional.

Type of Use (Select one or both, as applicable)

☐ Prescription Use (Part 21 CFR 801 Subpart D)

☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) SUMMARY

This summary document is being prepared in accordance with section 21 CFR 807.92.

The submitter of the 510(k) is:

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Date Summary Prepared: 20-Jan-2015

Device Subject to this 510(k):

Trade Name: CLEAR CARE® PLUS Cleaning & Disinfecting Solution

Common Name: Cleaning and Disinfecting Solution

Classification Name: Soft (hydrophilic) contact lens care products (886.5928);
Rigid gas permeable contact lens care products (886.5918)

Product Code: LPN

Predicate Device(s)

The 510(k) device, Hydrogen Peroxide nEOBO FID 120947A (i.e., FID 120947A), is a modification of the predicate device, Clear Care® Cleaning & Disinfecting Solution, a legally commercialized device in the US per the following US FDA 510(k) clearances: K003345, 26-Mar-2001; K013512, 20-Dec-2001; K022687, 19-Nov-2002; K023455, 28-Feb-2003; K030522, 12-Sep-2003; and K031521, 27-Jun-2003. In addition, other legally marketed devices to which substantial equivalence was demonstrated include Bausch + Lomb renu®

fresh™ multi-purpose solution [510(k) clearance K020802, 31-May-2002], and Boston Simplus® Multi-Action Solution [510(k) clearance K024289, 02-May-2003].

Device Description

FID 120947A is a sterile solution containing micro-filtered hydrogen peroxide 3% as the active ingredient. The formulation contains dual surfactants, Pluronic® 17R4 and a novel block copolymer surfactant, EO₁₀BO₅, composed of ethylene oxide and butylene oxide (nEOBO), to enhance wettability of contact lens surfaces. The formulation also contains phosphonic acid, a metal chelating agent to stabilize hydrogen peroxide, sodium phosphates as buffering agents, and sodium chloride as a tonicity agent. The sterile solution is aseptically filled and packaged in sterilized plastic bottles [gamma irradiated bottle; ethylene oxide (EtO) snap cap) with a tamper-evident seal and labeling to include the manufacturing lot number and expiration date. A special lens case, consisting of a transparent cup and connected unit of screw cap, lens holders (baskets) and platinum-coated neutralizing disc, is provided with each purchase of FID 120947A. The lens case is the same as that provided with the previously cleared device.

Indications for Use

Clear Care® Plus Cleaning & Disinfecting Solution is indicated for use in simultaneous cleaning, daily protein removal, disinfection, and storing of soft (hydrophilic) contact lenses (including silicone hydrogel lenses) and rigid gas permeable (fluoro silicone acrylate and silicone acrylate) contact lenses, as recommended by your eye care professional.

Brief Summary of Nonclinical Tests and Results

A series of pre-clinical and clinical studies were completed to demonstrate the substantial equivalence of FID 120947A to the predicate device(s). Testing was conducted in consideration of the May 1997 FDA *Guidance for Industry: Premarket Notification 510(k) Guidance Document for Contact Lens Care Products* and applicable ISO and ANSI standards for contact lens care solutions.

- **Residual Hydrogen Peroxide and Area under Curve**

The neutralization profile of FID 120947A was conducted for 100 cycles and found to be equivalent to Clear Care[®] in terms of residual hydrogen peroxide level, post neutralization and pH and osmolality. In addition, the area under the curve, a measurement of the total peroxide exposure available to kill microorganisms, for FID 120947A demonstrates an effective neutralization rate of peroxide.

- **Cleaning**

Studies were conducted to demonstrate the cleaning efficacy of FID 120947A with hydrogel and silicone hydrogel soft contact lenses and rigid gas permeable (RGP) lenses. The cleaning efficacy study using an exaggerated *in vitro* lysozyme demonstrates the ability of FID 120947A to clean protein from all hydrogel and silicone hydrogel soft contact lenses and rigid gas permeable (RGP) contact lenses.

A second *in vitro* cleaning efficacy study was conducted with three different soft contact lens materials, using physiologically relevant multi-component artificial tear fluid solution. The study further demonstrates the ability of FID 120947A to clean protein from soft contact lenses.

In addition, the ability of cleaning efficacy of the solution was evaluated through the determination of the critical micelle concentration (CMC). The surfactant concentration in the formulation was determined to exceed the CMC value.

- **Lens Compatibility**

Compatibility studies of FID 120947A were conducted with Groups I, II and IV traditional hydrogel soft contact lenses, Group V silicone hydrogel soft contact lenses and RGP contact lenses. Results demonstrate that FID 120947A is compatible with all hydrogel and silicone hydrogel soft contact lenses and RGP contact lenses.

- **Microbiology**

A series of studies was performed, based on the May 1997 FDA (510(k)) guidance document for contact lens care products, ANSI Z80.18-2010 (*Contact Lens Care Products –Vocabulary, Performance, Specifications and Test Methodology*), EN ISO

14729:2001/A1:2010 (*Ophthalmic Optics - Contact Lens Care Products - Microbiological Requirements and Test Methods for Products and Regimens for Hygienic Management of Contact Lenses*) and EN ISO 14730:2000 (*Ophthalmic optics- Contact Lens Care Products - Antimicrobial Preservative Efficacy Testing and Guidance on Determining Discard Date*), to demonstrate the microbiological efficacy of FID 120947A. Results demonstrated that the formulation meets the criteria for disinfection and preservative efficacy. In addition, FID 120947A met the requirements of ISO/FDA disinfecting regimen procedure for all nine contact lens materials tested.

- **Biocompatibility**

A complete battery of pre-clinical safety evaluations was conducted to ensure the safety of FID 120947A. Included in this battery were tests for genotoxicity, cytotoxicity, sensitization, systemic toxicity and ocular biocompatibility. Testing was conducted according to the May 1997 FDA 510(k) guidance document for contact lens care products and ISO 10993-1:2009/Cor. 1:2010 and related ISO biocompatibility standards. Acceptable results from this comprehensive series of *in vitro* and *in vivo* testing support the safety of FID 120947A for its intended use.

- **Clinical**

Two clinical studies were conducted to evaluate the safety and efficacy of FID 120947A in silicone hydrogel, traditional hydrogel and RGP contact lens wearers. In the first study, the control product was Bausch + Lomb renu[®] fresh[™] multi-purpose solution; and in the second study the control product was Boston Simplus[®] Multi-Action Contact Lens Solution. Upon review of the clinical results, FID 120947A was found to be at least as safe and effective as renu[®] fresh[™] for hydrogel and silicone hydrogel soft contact lenses; and Boston Simplus[®] for RGP contact lenses.

- **Substantial Equivalence Conclusion**

The cumulative results of all testing demonstrate the safety, efficacy and performance of FID 120947A and, thus, substantial equivalence to the predicate device(s) for cleaning and disinfection of hydrogel and silicone hydrogel soft contact lenses and rigid gas permeable (RGP) contact lenses.